



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robert K. Evans et.al.

Serial No. 10/578,955 ✓

Filed: May 10, 2006

For: PRESERVATIVE-CONTAINING VIRUS
FORMULATIONSArt Unit: 1648Examiner: to be assignedCommissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By C. Rapucki Date 7-12-07

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Henry P. Wu

Attorney _____ For Applicant(s)

Reg. No. 44,412

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-5312

Date: July 12, 2007

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

COMPLETE IF KNOWN

Attorney Docket Number	21575P
------------------------	--------

Sheet

1

of

2

Attorney Docket Number

21575P

[illegible]

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	B01	PCT	WO 98/02522		Transgene S.A.	01/22/1998
	B02	PCT	WO 99/41416		Schering Corporation	08/19/1999
	B03	PCT	WO 00/61726		Aventis Pharma SA	10/19/2000
	B04	PCT	WO 01/66137		Merck & Co., Inc.	09/13/2001
	B05	PCT	WO 01/02607		Merck & Co., Inc.	01/11/2001
	B06	PCT	WO 02/22080		Merck & Co., Inc.	03/21/2002

Date
Considered

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/28/2007

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/28/2007

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
			Application Number	10/578,955	
			Filing Date	May 10, 2006	
			First Named Inventor	Evans, Robert, K.	
			Group Art Unit	1648	
			Examiner Name	to be assigned	
Sheet	2	of	2	Attorney Docket Number	21575P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	C01	Brody et al. "Adenovirus-Mediated In Vivo Gene Transfer", Annals New York Academy of Sciences, Vol. 716, pp 90-101 (1994)
	C02	Croyle et al. "Factors that Influence Stability of Recombinant Adenoviral Preparations for Human Gene Therapy", Pharmaceutical Development and Technology, 3(3), pp 373-383 (1998)
	C03	Gray et al. "Compatibility of Various Preservatives with Live Virus Vaccines", International Symposium on Preservatives in Biological Products, Develop. Biol. Standard., Vol. 24, pp 123-129 (1974)
	C04	Hierholzer et al. "Adenoviruses from Patients with AIDS: A Plethora of Serotypes and A Description of Five New Serotypes of Subgenus D (Types 43-47)", The Journal of Infectious Diseases, Vol. 158, No. 4, pp 804-813 (October 1988)
	C05	Horne et al. "The Icosahedral Form of an Adenovirus", J. Mol. Biol. pp 84-86 (1959)
	C06	Horwitz et al. "Adenoviridae and Their Replication", in Fields Virology, Second Edition, pp 1679-1721, ((1990)
	C07	Jong et al. "Adenoviruses from Human Immunodeficiency Virus-Infected Individuals, Including Two Strains that Represent New Candidate Serotypes Ad50 and Ad51 of Species B1 and D, Respectively", Journal of Clinical Microbiology, Vol. 37, No. 12, pp 3940-3945, (1999)
	C08	Kebbe "Chlorobutanol", Handbook of Pharmaceutical Excipients, 3rd Ed., pp 126-128, (2000)
	C09	Kowalski et al. "The Survival of Adenovirus in Multidose Bottles of Topical Fluorescein", Amercian Journal of Ophthalmology, Volume 126, Issue 6, pp 835-836, (December 1998)
	C10	Nair et al. "The Kinetics of Degradation of Chlorobutanol", J. Am. Pharmaceutical Assoc., Volume XLVII, pp 390-395, (1959)
	C11	NyBerg-Hoffman et al. "Instability of Adenoviral Vectors during Transport and its Implication for Clinical Studies", Nature Medicine Inc., Volume 5, Number 8, pp 955-956, (August 1999)
	C12	Romanowski et al. "The Survival of Herpes Simplex Virus in Multidose Office Ophthalmic Solutions", Volume 128, Issue 2, pp 239-240, (August 1999)
	C13	Schurr et al. "Two New Candidate Adenovirus Serotypes", Intervirology, Vol. 36, pp 79-83, (1993)
	C14	Straus et al. "Adenovirus Infections in Humans", in The Adenoviruses, Plenum Press, pp 451-496, (1984)
	C15	Wadell et al. "Genetic Variability of Adenoviruses", Annals New York Academy of Sciences, Vol. 354, pp 16-42, (1980)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/28/2007